

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/100,633 06/19/98 HUTCHENS T 016866-00220

HM12/0901

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EXAMINER

WESSENDORF, T

ART UNIT 1627

13

DATE MAILED:

09/01/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/100,633	Applicant(s) Hutchens et al
Examiner T. W. Ssendorf	Group Art Unit 1627

Responsive to communication(s) filed on 6/12/00

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

Claim(s) 30 and 33-75 is/are pending in the application.

Of the above, claim(s) 34, 35, 37-41, 43-45, 47, 48, 50-53, 55-57, 59-62, 65, and 66 is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 30, 33, 36, 42, 46, 49, 54, 58, 63, 64, and 67-75 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30, 33, 67-69 and 70-75 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide an adequate written description of the various components in order to reasonably practice the claimed method. The specification merely provides an unspecified description of the claimed components. For example, page 24, lines 1-6 defines the agent as a chemical compound, a mixture of chemical compounds, a sample of undetermined composition and etc. An agent of undetermined composition encompasses myriads of agents to which the specifically exemplified single agent of known composition would provide only but one component of the claimed method that would not be an

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adequate description of an infinite numbers of agents, as claimed. Thus, the claims cover too numerous undefined or incompletely described parameters besides the agent such as the target analyte, substrate, adsorbent, ligand or receptor and more importantly, the conditions for the specific interactions of the different unspecified components to occur. Given the single embodies species which describes only a part of the invention, the specification, specifically, Example X1, which should supposedly directs or aids a skilled artisan to the various infinite variables covered by the claimed invention. It is not apparent from the specification how can one be led to a particular combinations of the various parameters such as the agent, target analyte, substrate or adsorbent and reaction or elution conditions for the successful practice of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30, 33, 67-69 and 70-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out

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and distinctly claim the subject matter which applicant regards as the invention.

A). Claim 30 is indefinite in that the method steps do not contain a method step by which screening occurs. The preamble recites for a method for screening but the body of the claims recite for steps for determining whether the agent modulates the reaction between a target analyte and an adsorbent. Incorporating the limitation of claim 33 would obviate this rejection.

B). Claim 33 is indefinite and confusing in the recitation of "each of a plurality of agents in a library" as it is unclear whether the combinatorial library contains a single agent or a collective or aggregate(plurality) of agents.

C). The use of different terminologies "substrate", "adsorbent" (claim 33); "ligand" (claim 71); "probe" (claim 74) to all mean the same thing provides for confusion and ambiguity? Does the substrate comprise different discrete components attached independently of one another or linked to one another (claim 71)? How can the substrate as an adsorbent be adapted as a probe or

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a location be predetermined (claim 74)? Within the claimed context, in what respect the probe is adapted for a desorption spectrometer or the basis by which the different locations can be predetermined (claim 74)?

D). Claim 70 is indefinite in the recitation of an agent as a "drug candidate". Within the claimed context, how is a drug considered to be a candidate or the basis by which a drug becomes a candidate? What are the steps necessary to identify a drug, as a candidate drug, especially in the absence of positive recitation or showing in the specification.

E). Claim 72 is unclear, within the claimed context, as to how the ligand being an antibody can be specific to the target protein. It is suggested that the claim recites for a monoclonal antibody as this is the antibody that provides a specificity action to the target protein.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

a person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 30, 33, 36, 42, 49, 54, 63, 67, 68, 70, 74 are rejected under 35 U.S.C. 102(a) as being anticipated by Siegel et al (Abstract, J. Mass Sepctrom.) [Note the footnotes at page 264, col. 1 which recites the presentation of the published work at the 44th ASMS conference on May 12-16/1996.]

The claimed method of identifying an agent that modulates interaction between an adsorbent and a target analyte by adsorbing the target analyte to the adsorbent and detecting the interaction or modulation effect of the agent by spectrometry is fully met by the process of Siegel, as described in the abstract.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 30, 33, 36, 42, 46, 49, 54, 58, 63-64, 67-69 and 70-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siegel in view of Kauvar (WO 89/09088).

Siegel is discussed, above. Siegel does not teach an antibody as the ligand i.e., adsorbent. However, Kauvar discloses a method of screening a polypeptide agent such as antibody and the use of paralogs i.e., agents to inhibit binding of antibody to antigen. See e.g., at e.g., page 5, lines 23-31; page 14, lines 7-35. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was

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made to use an antibody as the adsorbent in the method of Siegel, if one desires determining an antibody-antigen reaction. As shown by Kauvar such binding using affinity or solid chromatography would be applicable to different compounds such as antibody, enzyme or DNA. One would have been motivated to use spectrometric analysis coupled with adsorption chromatography since the combination of said two methods would obviously results in identifying or better characterization of a desired product.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1627.

Certain papers related to this application may be submitted to Art Unit 1627 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 O.G. 61 (November 16, 1993) and 1157 O.G. 94 (December 28, 1993) (see 37 C.F.R. 1.6(d)).

The official fax telephone numbers of the Group

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are (703) 308-7924. NOTE: If applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Mon. to Fri. from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat Ph.D., can be reached on (703) 308-0570. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

T. Wessendorf
T. Wessendorf
Patent Examiner
Art Unit 1627
8/28/00